

MAILLAND  
Appl. No. 10/559,794  
January 8, 2009

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 25-29 and 48-80 are in the case.

#### **I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Mr. Tate) for kindly agreeing to an interview in this case. The interview was held on January 6, 2009 and the courtesies extended by the Examiner were most appreciated. The substance of the interview will be clear from the Interview Summary and the comments presented below.

#### **II. THE ANTICIPATION REJECTION**

Claims 25, 26, 49, 58, 63, 65, 67, 68, 71-73, and 78 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Godbout (US 2004/00 13622). That rejection is traversed.

As discussed during the interview, claim 25 has been amended to specify that the claimed method is for the treatment of onychoschizia in a patient having onychoschizia. The method of amended claim 25 comprises administering to the patient a topical composition comprising (a) at least one herb extract from the genus Equisetum, and (b) at least one film forming agent.

Agreement was reached that the method as now claimed is not anticipated by Godbout since that reference contains no mention of onychoschizia or treatment of a patient having that condition by way of the claimed methodology. Withdrawal of the anticipation rejection is accordingly respectfully requested.

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### III. THE OBVIOUSNESS REJECTIONS

Claims 25, 26, 49, 58, 63, 65, 67, 68, 71-73, and 78 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Godbout and the admitted state of the art. This rejection is respectfully traversed.

The claimed invention is directed to a method for the treatment of onychoschizia in a patient having onychoschizia, which method comprises administering to the patient a topical composition comprising:

- a) at least one herb extract from the genus Equisetum, and
- b) at least one film forming agent.

Godbout is irrelevant for the reasons discussed above, namely that Godbout fails to disclose or suggest anything to do with the treatment of onychoschizia. With regard to the alleged "admitted state of the art", it appears from the Action that reference is being made to the statement in the specification that onychoschizia is a wide-spread condition found in 27-35% of normal adult women, affecting mainly housewives, workmen, and workwomen, and that exogenous factors that contribute to onychoschizia include people who carry out a great deal of housework including those whose nails are repeatedly soaked in water and then dried. While this may reflect the state of the art when the case was filed, the combination of this state of the art with Godbout does not give rise to a *prima facie* case of obviousness of the presently claimed method because there is no suggestion in those two disclosures of a method of treating a patient having the **specific condition known as onychoschizia** by administering a topical composition to the nail comprising (a) at least one herb extract from the genus

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*Equisetum*, and (b) at least one film forming agent. Absent any mention in either disclosure of treatment of onychoschizia, no *prima facie* case of obviousness arises.

As described in the present specification (pages 3 and 4), and as confirmed by the Mailland declaration referring to Enclosure 1 (copy attached to the Mailland declaration), onychoschizia is **not** a generic condition of nail brittleness, but rather a specific and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally. The Mailland declaration states that while the PDR for Herbal Medicine (PDR) reports that *Equisetum* may be used for the treatment of "brittle finger nails and loss of hair", the efficacy of such use "is not proven". Moreover, there is no suggestion in PDR to apply *Equisetum* topically onto nails in the treatment of onychoschizia.

The Mailland declaration goes on to state that onychomycosis and onychoschizia are "different and unrelated conditions", and require "two completely different treatments". In particular, as stated in the Mailland declaration referring to Enclosure 2 (copy attached to the Mailland declaration), and as discussed during the interview, onychomycosis is a fungal infection of the nails, caused by specific microorganisms and its treatment requires the use of antimycotic agents. In this pathology, the nail structure is damaged by the fungi that grow inside the nail and render the nail more fragile. The Mailland declaration states that onychomycosis is never a cause of onychoschizia, but it is frequently a cause of onycholysis, i.e., a detachment of the full nail plate from the nail bed.

The Mailland declaration then discusses Example 10 of the present application, which describes the results of a study of subjects previously affected by onychomycosis.

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The Mailland declaration notes that, after treatment with the claimed composition, no effect was seen in these subjects regarding onycholysis, whereas a definite improvement was recorded with onychoschizia (a significant improvement ( $p < 0.001$ ) was observed compared to untreated nails).

Onychoschizia is therefore understood in the art to be a **specific** and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally, **not** a generic condition of nail brittleness. This is described in the present specification at paragraphs [0008] and [0012].

Neither Godbout nor the state of the art as discussed in the present application relates to or suggests the treatment of onychoschizia by the claimed method. Moreover, the combination of those two disclosures fails to give rise to a *prima facie* case of obviousness of the claimed invention. Withdrawal of this obviousness rejection is respectfully requested.

Claims 27-29, 48, 51-62, 64, 66-70, and 74-79 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Godbout in view of the admitted state of the art as applied to claims 25, 26, 49, 63, and 71-73 above, and further in view of Ramin (US 5,607,768) and Moeller et al (DE 19826953 - WPINDEX Abstract), and further in view of the PDR® for Herbal Medicines (1998) and Koniger (WO 94/25041 - Derwent abstract and machine English translation). The rejection is respectfully traversed.

The deficiencies of Godbout are discussed above. Moreover, in Godbout, the generic brittle nail condition is treated by "massaging" the nail so as to promote penetration of the compositions into the nails (see paragraphs 0038, 0047 and claim 43). This is to be contrasted with the present invention wherein in treatment of the

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onychoschizia, the composition applied to the nail forms a matte, non-sticky and plastic film which strongly adheres to the nail (see Examples 1, 7, 8, and 9 of the present application). In other words, the composition employed in the claimed method is not and cannot be massaged in this way.

The alleged admitted state of the art, alone or in combination with Godbout, does not suggest the claimed invention for the reasons discussed above. In view of this, it is clear that the remaining secondary art cited in the Action (Ramin, Moeller, PDR for Herbal Medicines (1998) and Koniger) does not give rise to a *prima facie* of obviousness of the claimed method taken alone or in combination with Godbout. Withdrawal of this obviousness rejection is respectfully requested.

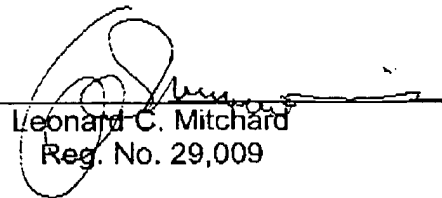
New independent claim 80 is presented which recites the presence of least one water soluble film forming agent which is a derivative of chitosan. No new matter is entered.

Favorable action is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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